

AMENDED IN SENATE JULY 8, 2015
AMENDED IN SENATE JUNE 9, 2015
AMENDED IN ASSEMBLY APRIL 28, 2015
AMENDED IN ASSEMBLY APRIL 6, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 1073

Introduced by Assembly Member Ting

February 27, 2015

An act to *amend Section 4199 of*, and to add Section 4076.6 to to, the Business and Professions Code, and to add Section 1714.20 to the Civil Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1073, as amended, Ting. Pharmacy: prescription drug labels.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. That law requires the board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California. Existing regulations of the board implement that ~~requirement~~. *requirement, establishing standardized directions for use to be used when applicable, and requiring that the board publish on its Internet Web site translation of those directions for use into at least 5 languages other than English.* A violation of that law is a crime.

This bill would require a dispenser, ~~in his or her professional judgment, to use a standardized direction for use on the label of the prescription container from a list in existing regulations.~~ The bill would

~~require the board to make available translations, in a minimum of 5 languages other than English, of those standardized directions for use and post the translated standardized directions for use on its Internet Web site. This bill would require the board to allow a dispenser 180 days to implement changes to translated standardized directions as may be adopted by the board. The bill would require a dispenser, upon request of a patient for a translated direction for use, to select the appropriate translated standardized direction for use, if available, and append it to the label on the patient's prescription container or provide it on a supplemental document. The bill would authorize a dispenser to provide his or her own translated directions, in any language other than English, as an alternative to the translations made available by the board and the above-described procedure. *excluding a veterinarian, upon the request of a patient or patient's representative, to provide translated directions for use as prescribed. The bill would authorize a dispenser to use translations made available by the board pursuant to those existing regulations. The bill would make a dispenser responsible for the accuracy of English-language directions for use provided to the patient.* By imposing new requirements on dispensers, the violation of which would be a crime, this bill would impose a state-mandated local program.~~

~~The bill would exempt from civil liability a dispenser who complies with the requirement to select the appropriate translated standardized direction for use, if available, and append it to the label, for any error that results from the inability of the dispenser to understand a translated direction for use in a language other than English.~~

~~The Pharmacy Law also provides for the licensure and regulation of veterinary food-animal drug retailers by the board. That law subjects to specific prescription drug labeling requirements any veterinary food-animal drug dispensed pursuant to a prescription from a licensed veterinarian for food-producing animals from a veterinary food-animal drug retailer pursuant to that law.~~

~~This bill would also subject any veterinary food-animal drug so dispensed to the above drug labeling requirements relating to standardized directions for use.~~

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 ~~SECTION 1. Section 4076.6 is added to the Business and~~
2 ~~Professions Code, to read:~~

3 ~~4076.6. (a) For all dangerous drugs dispensed to patients in~~
4 ~~this state, when applicable and in the professional judgment of the~~
5 ~~dispenser, a dispenser shall use a standardized direction for use~~
6 ~~on the label of the prescription container from the list in subdivision~~
7 ~~(a) of Section 1707.5 of Title 16 of the California Code of~~
8 ~~Regulations.~~

9 ~~(b) The board shall make available translations, in a minimum~~
10 ~~of five languages other than English, of the standardized directions~~
11 ~~for use that are listed in subdivision (a) of Section 1707.5 of Title~~
12 ~~16 of the California Code of Regulations. These translations shall~~
13 ~~be approved by qualified translators, as determined by the board.~~
14 ~~The board shall post these translated standardized directions for~~
15 ~~use on its Internet Web site. The board shall allow a dispenser a~~
16 ~~period of 180 days from the date of adoption by the board of any~~
17 ~~change to the translated standardized directions for use to~~
18 ~~implement that change.~~

19 ~~(c) Upon the request of a patient for a translated direction for~~
20 ~~use, a dispenser shall select the appropriate translated standardized~~
21 ~~direction for use from those established in accordance with~~
22 ~~subdivision (b), if available, and append it to the label on the~~
23 ~~patient's prescription container or provide it on a supplemental~~
24 ~~document. If a translated direction for use appears on a prescription~~
25 ~~container label, the English version of the direction shall also~~
26 ~~appear on the container. The translated direction for use shall~~
27 ~~appear in the patient-centered area of the label in accordance with~~
28 ~~subdivision (a) of Section 1707.5 of Title 16 of the California Code~~
29 ~~of Regulations. The English version may appear in an area of the~~
30 ~~label outside the patient-centered area.~~

31 ~~(d) A dispenser may provide his or her own translated directions,~~
32 ~~in any language other than English, as an alternative to the~~
33 ~~translations made available by the board and the procedure~~
34 ~~established in subdivisions (a) to (c), inclusive. The translated~~
35 ~~directions for use shall appear in the patient-centered area of the~~

1 label in accordance with subdivision (a) of Section 1707.5 of Title
2 16 of the California Code of Regulations or a supplemental
3 document. If a translated direction for use appears on a prescription
4 container label, the English version of the direction shall also
5 appear on the container. The English version may appear in other
6 areas of the label outside the patient-centered area.

7 SEC. 2. ~~Section 1714.20 is added to the Civil Code,~~
8 ~~immediately following Section 1714.2, to read:~~

9 1714.20. (a) ~~A dispenser who complies with subdivision (c)~~
10 ~~of Section 4076.6 of the Business and Professions Code shall not~~
11 ~~be liable for civil damages for any error that results from the~~
12 ~~inability of the dispenser to understand a translated direction for~~
13 ~~use in a language other than English.~~

14 (b) ~~This section does not affect existing liability under this~~
15 ~~division for translated directions not approved by the California~~
16 ~~State Board of Pharmacy.~~

17 SECTION 1. *Section 4076.6 is added to the Business and*
18 *Professions Code, to read:*

19 4076.6. (a) *Upon the request of a patient or patient's*
20 *representative, a dispenser shall provide translated directions for*
21 *use, which shall be printed on the prescription container, label,*
22 *or on a supplemental document.*

23 (b) *A dispenser may use translations made available by the*
24 *board pursuant to subdivision (b) of Section 1707.5 of Title 16 of*
25 *the California Code of Regulations to comply with this section.*

26 (c) *A dispenser shall not be required to provide translated*
27 *directions for use beyond the languages that the board has made*
28 *available or beyond the directions that the board has made*
29 *available in translated form.*

30 (d) *Nothing in this section shall be construed to prohibit a*
31 *dispenser from providing translated directions for use in languages*
32 *beyond those that the board has made available or beyond the*
33 *directions that the board has made available in translated form.*

34 (e) *A dispenser shall be responsible for the accuracy of the*
35 *English-language directions for use provided to the patient.*

36 (f) *For purposes of this section, a dispenser does not include a*
37 *veterinarian.*

38 SEC. 2. *Section 4199 of the Business and Professions Code is*
39 *amended to read:*

1 4199. (a) Any veterinary food-animal drug dispensed pursuant
2 to a prescription from a licensed veterinarian for food producing
3 animals from a veterinary food-animal drug retailer pursuant to
4 this chapter is subject to the labeling requirements of Sections
5 ~~4076~~ 4076, 4076.6, and 4077.

6 (b) All prescriptions filled by a veterinary food-animal drug
7 retailer shall be kept on file and maintained for at least three years
8 in accordance with Section 4333.

9 SEC. 3. No reimbursement is required by this act pursuant to
10 Section 6 of Article XIII B of the California Constitution because
11 the only costs that may be incurred by a local agency or school
12 district will be incurred because this act creates a new crime or
13 infraction, eliminates a crime or infraction, or changes the penalty
14 for a crime or infraction, within the meaning of Section 17556 of
15 the Government Code, or changes the definition of a crime within
16 the meaning of Section 6 of Article XIII B of the California
17 Constitution.